

**In the Matter Of:**

NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY

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**DEPOSITION OF**  
**SHMUEL SHOHAM, M.D.**

*January 19, 2017*

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1201 West Peachtree Street  
Suite 2300  
Atlanta, GA 30309  
404.847.0999

NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY  
SHMUEL SHOHAM, M.D. on 01/19/2017

DEPOSITION OF

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND :  
COMPOUNDING PHARMACY, INC. :  
PRODUCTS LIABILITY LITIGATION: MDL NO. 2419  
:  
This Documents Relates to: : Master Docket  
: 1:13-MD-02419-RWZ  
All Cases against the Box :  
Hill Defendants :  
:  
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DEPOSITION OF  
SHMUEL SHOHAM, M.D.

THURSDAY, JANUARY 19, 2017  
10:00 a.m.

Law Office of Peter G. Angelos  
One Charles Center  
100 North Charles Street  
Suite 2200  
Baltimore, MD 21201

Before: Linda Bahur, RPR



1201 West Peachtree Street  
Suite 2300  
Atlanta, GA 30309  
404.847.0999  
www.DiscoveryLit.com

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Pages 2..5

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Page 5

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Page 3

Page 5

NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY  
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DEPOSITION OF  
Pages 42..45

<p style="text-align: right;">Page 42</p> <p>1 going to give opinions about -- you were going to give</p> <p>2 opinions concerning being a medical doctor, in</p> <p>3 general, not a pain specialist?</p> <p>4 MS. KASPUTYS: Objection.</p> <p>5 A That's what we talked about. But they</p> <p>6 weren't telling me what to do. They were saying that</p> <p>7 that is something that I can do.</p> <p>8 Q They said it's something you can do?</p> <p>9 A As I recall. I don't recall the specific</p> <p>10 words.</p> <p>11 Q And did that have to do with standard of</p> <p>12 care or what did it have to do with?</p> <p>13 A Standard of care.</p> <p>14 Q So why don't you give me your opinions with</p> <p>15 regards to that, as a medical doctor, and how it</p> <p>16 relates to a standard of care in this case.</p> <p>17 A So my opinions regarding standard of care</p> <p>18 in this case are in the report.</p> <p>19 Q Okay. But can you point me to where it is?</p> <p>20 A Page 3 is a specific example.</p> <p>21 Q What part of page 3?</p> <p>22 A Third paragraph.</p> <p>23 Q Okay. So let's look at the first</p> <p>24 paragraph, the first full paragraph on page 3. It</p> <p>25 says, "The manner by which the contaminated steroids</p>	<p style="text-align: right;">Page 44</p> <p>1 applicable to prescribing prescription medicines," and</p> <p>2 then describes, I guess, some other opinions in here.</p> <p>3 But what Maryland law are you referring to?</p> <p>4 A I can give you -- the specific newsletter</p> <p>5 is number 13 on page 5, Board of Pharmacy Newsletter,</p> <p>6 Fall 2012.</p> <p>7 Q Okay. Do you have a copy of that?</p> <p>8 MS. KASPUTYS: That's in the documents that</p> <p>9 were produced for you. Third tab.</p> <p>10 MR. COREN: Third tab?</p> <p>11 MR. KIRBY: I'm not saying you didn't send</p> <p>12 it out. I'm just saying I don't see a copy of it.</p> <p>13 MS. KASPUTYS: Greg, I'll give you one to</p> <p>14 look at.</p> <p>15 MR. KIRBY: Okay.</p> <p>16 MS. KASPUTYS: If I can get it out of the</p> <p>17 binder. There you go.</p> <p>18 MR. KIRBY: Thanks.</p> <p>19 MS. KASPUTYS: Oh, wait a minute. Let me</p> <p>20 give you the rest of the pages. There you go.</p> <p>21 MR. KIRBY: I'd like to mark this as an</p> <p>22 exhibit. Can we make a copy?</p> <p>23 MS. KASPUTYS: Go ahead. You can use that.</p> <p>24 Just take it. I have a stapler if you need one.</p> <p>25 BY MR. KIRBY:</p>
<p style="text-align: right;">Page 43</p> <p>1 reached patients did not always conform to the</p> <p>2 standards of care. A specific example is the method</p> <p>3 and manner in which PF MPA from NECC was prescribed,</p> <p>4 ordered, and administered at Box Hill Surgery Center</p> <p>5 in Maryland."</p> <p>6 So what do you mean by that? Like, be more</p> <p>7 specific.</p> <p>8 A So the way that the products were</p> <p>9 prescribed, according to the testimony that I've read,</p> <p>10 were that patients who had previously been seen at the</p> <p>11 surgical center, their names were provided as a list</p> <p>12 and vials were ordered using those names.</p> <p>13 And then those vials would come and those</p> <p>14 vials were sometimes given to patients who were</p> <p>15 different than the ones that it was prescribed for.</p> <p>16 And additionally, the single use vials were at times</p> <p>17 used more than one time for one patient for one</p> <p>18 procedure.</p> <p>19 Q Okay. You've never purchased drugs for an</p> <p>20 ambulatory surgery center before, right?</p> <p>21 A Not that I recall.</p> <p>22 Q Okay. And you don't generate, manage, and</p> <p>23 treat chronic pain patients, correct?</p> <p>24 A That is correct.</p> <p>25 Q Now, it says in here "under Maryland law</p>	<p style="text-align: right;">Page 45</p> <p>1 Q Doctor, have you found the newsletter you</p> <p>2 were referring to in your binders?</p> <p>3 A Yes. It's on page 7 of the newsletter</p> <p>4 that's called "Maryland Board of Pharmacy News," Fall</p> <p>5 2012.</p> <p>6 Q I'm sorry, can you say that one more time?</p> <p>7 A Maryland Board of Pharmacy News, Fall 2012,</p> <p>8 page 7.</p> <p>9 Q Okay. So we're going to mark this, it's</p> <p>10 the same thing you have, as 1612-6, for the record.</p> <p>11 (Exhibit No. 1612-6 was marked for</p> <p>12 identification.)</p> <p>13 Q As a physician, you don't regularly receive</p> <p>14 newsletters from the Board of Pharmacy, do you?</p> <p>15 A I may. I'm not sure.</p> <p>16 Q Okay. You don't seek out and review</p> <p>17 newsletters from the Board of Pharmacy, do you?</p> <p>18 A In preparation for this case, I reviewed</p> <p>19 this material.</p> <p>20 Q So I mean, in the normal course of your</p> <p>21 practice.</p> <p>22 A I may receive it.</p> <p>23 Q You're talking about you receive Maryland</p> <p>24 Board of Pharmacy newsletters?</p> <p>25 A I may. I'm not sure.</p>

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DEPOSITION OF  
Pages 106..109

<p style="text-align: right;">Page 106</p> <p>1 for multiple patients or for multiple procedures in 2 the same patient is not standard of care. 3 Q Okay. And are you familiar with any 4 literature that suggests that, I guess, "single-dose 5 dose vials can be used on multiple patients under 6 certain circumstances with certain precautions that 7 are taken"? 8 A I have seen a reference that is an opinion 9 by some people. 10 Q Okay. So you wouldn't disagree that some 11 in medicine accept the practice of using single-dose 12 vials multiple times as long as they follow certain 13 precautions? 14 A That is an opinion. That is not what the 15 CDC recommends. The CDC recommends against it. 16 Q All right. If other reasonably prudent 17 practitioners believe that it's okay to do it as long 18 as there are certain precautions taken, isn't that the 19 definition of standard practice? 20 MR. COREN: Objection as to form. 21 MS. KASPUTYS: Object to form. 22 Q Maybe not everyone agrees. You have one. 23 Someone else has a different opinion. But that 24 doesn't mean that just because it's different than 25 your opinion that it's wrong, correct?</p>	<p style="text-align: right;">Page 108</p> <p>1 A Yes. 2 Q "And the push for cost-efficient care, a 3 case can made for safely reusing a single-dose 4 medication." See that? 5 A I see that. 6 Q And then under there, it's a description of 7 -- I'm just going to read it. You can follow along. 8 It says, "If a practitioner chooses to reuse a 9 single-dose medication, there must be strict 10 safeguards in place that minimize the risk of 11 infection. These include using the medication for a 12 limited number of patients and for a single day only, 13 cleansing the stopper thoroughly between uses with 14 isopropyl alcohol or another suitable antimicrobial. 15 Refrigeration of vial between cases if there is a time 16 gap between consecutive cases and discarding the vial 17 if any breach or sterility is suspected." 18 And then it goes on to say, of course, you 19 only, you know, use a needle, one needle per patient, 20 et cetera. 21 If that is the process by which Dr. 22 Bhambhani administers the drug and "reuses the 23 single-dose vial," she follows those precautions, 24 would you agree that according to this article, she's 25 complying with an accepted standard of practice?</p>
<p style="text-align: right;">Page 107</p> <p>1 A You said a lot of things there. 2 Q I did, didn't I? There's not always one 3 way to satisfy the standard of care, right? There's 4 sometimes more than one standard practice, right? 5 A As a general statement? 6 Q As general statement, right. 7 A There are different ways to do things. 8 Q And I want to just hand you what's been 9 previously marked as 1619-10. It's an article. At 10 the top, just for the record, that says it's titled 11 "The Price of Cost Savings," Ray M. Baker, in the 12 Clinical Journal of Pain, June of 2008. 13 And did you review in Dr. Bhambhani's 14 deposition her description of the process and how she 15 administers the injection and what precautions she 16 takes? 17 A Yes. 18 Q Okay. So if you look at the second page of 19 this article, page 382, if you look at the right 20 column, the second paragraph up from the bottom, it 21 starts off "If a practitioner chooses." 22 A Yes. 23 Q And actually if you look a few lines up 24 from that, it says, "Given the reduced reimbursements 25 for interventional pain procedures." Do you see?</p>	<p style="text-align: right;">Page 109</p> <p>1 MR. STEINER: Objection as to form. You 2 can answer. 3 A According to the CDC, in which I place more 4 credence than this opinion, a single vial, a 5 single-dose vial should not be reused. And I don't 6 know why this clinician opined as he did. But even in 7 2012, I would not say that this was a reasonable 8 opinion based on the history of multiple outbreaks 9 related with reusing of single-dose vials. 10 Q Do you know Dr. Baker? 11 A No. 12 Q Are you familiar with this journal? 13 A I've heard of it. 14 Q Do you have an opinion, one way or the 15 other, whether this journal is a reasonably reliable 16 journal? 17 MR. COREN: Objection as to form. 18 A I don't. 19 Q And so you would disregard the expressions 20 made here this literature? 21 A I do not think that the statement of given 22 the reduced reimbursements for interventional pain 23 procedures and the push for cost-efficient care, a 24 case can be made for safely reusing a single-dose 25 medication, and that this is something that could be</p>